DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-303 / S-019
NDA 21-977 / S-008

Shire Development, Inc.
Attention: Jennifer Pavillard
Associate Director Regulatory Affairs
725 Chesterbrook Blvd.
Wayne, PA 19087

Dear Ms. Pavillard:

Please refer to your supplemental new drug applications dated and received October 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adderall XR (dextroamphetamine mixed salts of a single-entity amphetamine product) capsules and Vyvanse (lisdexamfetamine dimesylate) capsules.

These supplemental new drug applications provide for the addition of the following statement to the product Medication Guide as required under 21 CFR 208.20(b)(7)(iii):

> "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088."

We have completed our review of these applications and they are approved effective on the date of this letter for use as recommended in the submitted labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDA 21-303 / S-019 and NDA 21-977 / S-008."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff at Steven.Hardeman@FDA.HHS.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of New Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren

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